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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,834	04/26/2006	Roberto A Macina	DEX-0532	8654

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EXAMINER	
AEDER, SEAN E	
ART UNIT	PAPER NUMBER
1642	
NOTIFICATION DATE	DELIVERY MODE
06/16/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

poreilly@licataandtyrrell.com

Office Action Summary	Application No.	Applicant(s)	
	10/523,834	MACINA ET AL.	
	Examiner	Art Unit	
	SEAN E. AEDER	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4/28/09*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19,21,22,25-27,29,30,33,34 and 43-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *19,21,22,25-27,29,30,33,34,43 and 44* is/are allowed.

6)☒ Claim(s) *45-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

The Amendments and Remarks filed 4/28/09 in response to the Office Action of 10/28/08 are acknowledged and have been entered.

Claims 43-56 have been added by Applicant.

Claims 19, 21, 22, 25-27, 29, 30, 33, 34, and 43-56 are pending.

Claims 19 and 27 have been amended by Applicant.

Claims 19, 21, 22, 25-27, 29, 30, 33, 34, and 43-56 are currently under examination.

The following Office Action contains NEW GROUNDS of rejections necessitated by amendments.

Rejections Withdrawn

All previous rejections are withdrawn.

New Rejections Necessitated by Amendments

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 45, 47-49, 51, and 53-55 are rejected under 35 U.S.C. 102(e) as being anticipated by Barry et al (WO 01/71358 A1; 9/27/01).

Claim 45 encompasses monoclonal antibodies, or antigen binding fragments thereof, that compete for binding to an epitope bound by antibody that specifically binds the antigenic region of amino acids 90-97 of SEQ ID NO:265 (DSVVYGLR) with an affinity of at least 1 X 10^{-6} M. Claim 47 is drawn to the antibody, or antigen binding fragment thereof, of claim 45 wherein the antibody, or antigen binding fragment thereof, is a humanized antibody. Claim 48 is drawn to the antibody, or antigen binding fragment thereof, of claim 45, wherein the antibody, or antigen binding fragment thereof, is a chimeric antibody. Claim 49 is drawn to the antibody, or antigen binding fragment thereof, of claim 45 wherein the antibody, or antigen binding fragment thereof, is labeled. Claim 51 encompasses monoclonal antibodies, or antigen binding fragments thereof, that specifically bind to the antigenic region of amino acids 90-97 of SEQ ID NO:265 (DSVVYGLR) with an affinity of at least 1 X 10^{-6} M. Claim 53 is drawn to the antibody, or antigen binding fragment thereof, of claim 51 wherein the antibody, or antigen binding fragment thereof, is a humanized antibody. Claim 54 is drawn to the antibody, or antigen binding fragment thereof, of claim 51, wherein the antibody, or antigen binding fragment thereof, is a chimeric antibody. Claim 55 is drawn to the antibody, or antigen binding fragment thereof, of claim 51 wherein the antibody, or antigen binding fragment thereof, is labeled.

Barry et al teaches monoclonal antibodies and antigen binding fragments thereof that specifically bind the following fragment of osteopontin: SVVYGLR (see paragraph

flanking pages 27-28, in particular). Because the fragment of Barry et al is within amino acids 90-97 of instant SEQ ID NO:265, one of skill in the art would recognize that the antibody of Barry et al would specifically bind amino acids 90-97 of instant SEQ ID NO:265 and would compete for binding to an epitope bound by every antibody that specifically binds the antigenic region of amino acids 90-97 of SEQ ID NO:265. Barry et al further teaches the antibody, or antigen binding fragment thereof, as a chimeric and humanized antibody (lines 16-23 on page 28, in particular). Barry et al further teaches the antibody, or antigen binding fragment thereof as labeled (line 15 on page 29, in particular). Although Barry et al not specifically teach said antibodies bind DSVVYGLR with an affinity of at least 1 X 10^{-6} M, the claimed product appears to be the same as the prior art because antibodies of a variety of affinities would be produced by the teachings of Barry et al including those that bind DSVVYGLR with an affinity of at least 1 X 10^{-6} M. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the antibodies of Barry et al bind the target taught by Barry et al with an affinity of at least 1 X 10^{-6} M. In the absence of evidence to the contrary, the burden is on Applicant to prove that the claimed product would not be produced by the teachings of Barry et al. See In re Best 562F .2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2^{nd} 1992 (PTO Bd. Pat. App. & Int. 1989).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 45-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barry et al (WO 01/71358 A1; 9/27/01) as applied to claims 45, 47-49, 51, and 53-55 above, and further in view of Muller et al (US 2003/0118585 A1; filed 10/17/01).

Teaching of claims 45, 47-49, 51, and 53-55 by Barry et al is discussed above.

Barry et al does not specifically teach antibodies bound to a toxin or said antibodies as human antibodies. However, these deficiencies are made up in the teachings of Muller et al.

Muller et al teaches antibodies that specifically bind osteopontin would be conjugated to a toxin for the treatment of tumors (see paragraphs 50-51 and 91-92, in particular). Muller et al further teaches human antibodies are preferably administered to humans because human antibodies produce less of an immune response when administered to humans (see paragraph 234, in particular).

One of ordinary skill in the art at the time the invention was made would have been motivated to produce human versions of the osteopontin-specific antibodies of Barry et al conjugated to a toxin because Muller et al teaches antibodies that specifically bind osteopontin would be conjugated to a toxin for the treatment of tumors (see paragraphs 50-51 and 91-92, in particular) and that antibodies are preferably administered to humans because human antibodies produce less of an immune response when administered to humans (see paragraph 234, in particular). One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for producing human versions of the osteopontin-specific antibodies of Barry et al conjugated to a toxin because Muller et al teaches conjugating antibodies that specifically bind osteopontin to a toxin for the treatment of tumors (see paragraphs 50-51 and 91-92, in particular) and Muller et al further teaches methods of producing human antibodies (see paragraph 234, in particular). Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results.

Claims 45, 47-49, 51, and 53-55 are rejected under 35 U.S.C. 103(a) as being anticipated by Barry et al (WO 01/71358 A1; 9/27/01) in view of Mukoyama et al (Hypertension, August 1988, 12(2): 117-121).

Claim 45 encompasses monoclonal antibodies, or antigen binding fragments thereof, that compete for binding to an epitope bound by antibody that specifically binds the antigenic region of amino acids 90-97 of SEQ ID NO:265 (DSVVYGLR) with an

affinity of at least 1 X 10^{-6} M. Claim 47 is drawn to the antibody, or antigen binding fragment thereof, of claim 45 wherein the antibody, or antigen binding fragment thereof, is a humanized antibody. Claim 48 is drawn to the antibody, or antigen binding fragment thereof, of claim 45, wherein the antibody, or antigen binding fragment thereof, is a chimeric antibody. Claim 49 is drawn to the antibody, or antigen binding fragment thereof, of claim 45 wherein the antibody, or antigen binding fragment thereof, is labeled. Claim 51 encompasses monoclonal antibodies, or antigen binding fragments thereof, that specifically bind to the antigenic region of amino acids 90-97 of SEQ ID NO:265 (DSVVYGLR) with an affinity of at least 1 X 10^{-6} M. Claim 53 is drawn to the antibody, or antigen binding fragment thereof, of claim 51 wherein the antibody, or antigen binding fragment thereof, is a humanized antibody. Claim 54 is drawn to the antibody, or antigen binding fragment thereof, of claim 51, wherein the antibody, or antigen binding fragment thereof, is a chimeric antibody. Claim 55 is drawn to the antibody, or antigen binding fragment thereof, of claim 51 wherein the antibody, or antigen binding fragment thereof, is labeled.

Barry et al teaches monoclonal antibodies and antigen binding fragments thereof that specifically bind the following fragment of osteopontin: SVVYGLR (see paragraph flanking pages 27-28, in particular). Because the fragment of Barry et al is within amino acids 90-97 of instant SEQ ID NO:265, one of skill in the art would recognize that the antibody of Barry et al would specifically bind amino acids 90-97 of instant SEQ ID NO:265 and would compete for binding to an epitope bound by every antibody that specifically binds the antigenic region of amino acids 90-97 of SEQ ID NO:265. Barry et

al further teaches the antibody, or antigen binding fragment thereof, as a chimeric and humanized antibody (lines 16-23 on page 28, in particular). Barry et al further teaches the antibody, or antigen binding fragment thereof as labeled (line 15 on page 29, in particular).

Barry et al not specifically teach said antibodies bind DSVVYGLR with an affinity of at least 1 X 10^{-6} M.

Mukoyama et al teaches methods of identifying high affinity antibodies with an affinity of at least 1 X 10^{-6} M for specific targets (see pages 118-119, in particular).

One of ordinary skill in the art at the time the invention was made would have been motivated to screen antibodies of Barry et al using methods of Mukoyama et al to obtain high affinity antibodies with an affinity of at least 1 X 10^{-6} M to DSVVYGLR because high affinity antibodies bind targets better than low affinity antibodies. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for screening antibodies of Barry et al using methods of Mukoyama et al to obtain high affinity antibodies with an affinity of at least 1 X 10^{-6} M to DSVVYGLR because Mukoyama et al teaches methods of identifying high affinity antibodies with an affinity of at least 1 X 10^{-6} M for specific targets (see pages 118-119, in particular). Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results.

Claims 45-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barry et al (WO 01/71358 A1; 9/27/01) in view of Muller et al (US 2003/0118585 A1; filed 10/17/01) and further in view of Mukoyama et al (Hypertension, August 1988, 12(2): 117-121).

The combined teaching of Barry et al and Muller et al is discussed above.

The combined teaching of Barry et al and Muller et al does not specifically teach said antibodies bind DSVVYGLR with an affinity of at least 1 X 10^{-6} M.

Mukoyama et al teaches methods of identifying high affinity antibodies with an affinity of at least 1 X 10^{-6} M for specific targets (see pages 118-119, in particular).

One of ordinary skill in the art at the time the invention was made would have been motivated to screen antibodies of Barry et al and Muller et al using methods of Mukoyama et al to obtain high affinity antibodies with an affinity of at least 1 X 10^{-6} M to DSVVYGLR because high affinity antibodies bind targets better than low affinity antibodies. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for screening antibodies of Barry et al and Muller et al using methods of Mukoyama et al to obtain high affinity antibodies with an affinity of at least 1 X 10^{-6} M to DSVVYGLR because Mukoyama et al teaches methods of identifying high affinity antibodies with an affinity of at least 1 X 10^{-6} M for specific targets (see pages 118-119, in particular). Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results.

Allowable Subject Matter

Claims 19, 21, 22, 25-27, 29, 30, 33, 34, 43, and 44 are allowed.

Summary

Claims 45-56 are rejected.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SEAN E. AEDER whose telephone number is (571)272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sean E Aeder/
Primary Examiner, Art Unit 1642